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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,586	12/29/2003	Martin R. Willard	1001.1714101	8579

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EXAMINER	
BRUENJES, CHRISTOPHER P	
ART UNIT	PAPER NUMBER
1772	

DATE MAILED: 08/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/750,586	WILLARD ET AL.	
	Examiner	Art Unit	
	Christopher P. Bruenjes	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 12-29* is/are pending in the application.

4a) Of the above claim(s) *26 and 27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,12-25,28 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 17, 2006 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-10 and 12-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 7, 12, 19, 24, and 25, at least the limitation that the proximal section includes about 91 to about 95wt% polyoxymethylene and claims 1, 7, 12, and 19, also include the limitation that the proximal section includes about 5 to about 9wt% polyether polyester. Narrowing the range of polyoxymethylene and polyether polyester in the proximal portion to a range between about 91 to about 95wt% and about 5 to about 9wt% respectively is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed had possession of the claimed invention. In order to narrow the range there must be some specific support provided in the original specification and not every narrower range within a broad range is automatically supported. In particular, in the decision in In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), cited by the applicant, the original specification had specific examples within the broad range of 25%-60% of 36% and 50%. It was these specific examples in combination with the broad range that provided support for narrowing the range to between 35% and 60%. Applicant's original specification provides no specific examples or any other values with a range

narrower than the originally claimed 80 to 95% and 5 to 20%. Therefore, the specification does not clearly disclose to one of ordinary skill in the art that the inventors considered the specific range to be part of their invention and is merely taking a broad invention taught in the original disclosure later filing claims to carve out a patentable portion that is not based on the originally filed invention. See MPEP 2163.05 III.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-10, 12-25, and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Itou et al (EP 1 068 876 A2) in view of Utsumi et al (USPN 5,258,160).

Regarding claims 1, 24, 25, 28, and 29, Itou et al teach a catheter shaft comprising a proximal portion, a distal portion, and an intermediate portion between the proximal and distal portions (col.3, l.23-27). A first resin layer is arranged in a first region of the tubular member and consists of a first resin material disposed in a dense spiral or mesh and a second resin material disposed in a sparse spiral or mesh, and a second resin layer is arranged in a second region of the tubular member and consists of the second resin material disposed in a dense spiral or mesh and the first resin material disposed in a sparse spiral or mesh. The intermediate region between the first and second regions consists of the first resin material disposed in a spiral or mesh of a disposing density intermediate between the disposing densities in the first and second regions and the second resin material disposed in a spiral or mesh in a disposing density intermediate between the disposing densities in the first and second regions (col.3, l.27-45). The first region represents the proximal portion and the second region

represents the distal portion of the catheter shaft (col.3, l.46-50). The first resin material has a flexural rigidity higher than that of the second resin material (col.4, l.23-25). Therefore, Itou et al teach that the proximal portion is predominantly a more rigid resin and the distal portion is predominantly a less rigid resin. After the spiral shaped material is disposed in the shaft the first and second materials are melted and mixed or fused and then solidified (col.4, l.26-33). Therefore, the layer is a blend of the two materials. Specifically, with regard to claims 28-29, the proximal portion has a concentration of the more rigid material within the claimed range of 80 to 95% by weight and a concentration of the less rigid material within the claimed range of 5 to 20% (col.10, l.32-37). Specifically, with regard to claims 1, 24, and 25, as admitted by the applicant, Itou teaches the ratio between the rigid member and flexible member in the proximal portion to be in a range having a minimum of 90.9% rigid and 9.1% flexible. Applicant's claims require about 91% to about 95% of rigid and about 5% to about 9% of flexible material. About is not specifically defined in Applicant's specification, however, by claiming about the range is slightly less than 91% and slightly more than 95%. Therefore, one of ordinary skill in the art would have recognized that 90.9% is about 91% and 9.1%

is about 9%. Therefore, Itou teaches the ranges claimed. The distal portion has a concentration of the more rigid material within the claimed range of 5 to 20% and a concentration of the less rigid material within the claimed range of 80 to 95% (col.10, l.38-43). The intermediate portion obviously has a concentration of the more rigid material within the claimed range of 20 and 50% and a concentration of the less rigid material within the claimed range of 50 to 80%, since the concentration of the two materials are values between the values of the concentration of the respective materials in the proximal and distal portions. The materials chosen for the formation of the blend material are a combination of at least two material chosen form a group that includes polyoxymethylene and polyester elastomers (col.9, l.13-30), in which the polyester elastomers is described as a polyether polyester (col.11, l.46-53). Regarding claims 2, 8, 13 and 20, the catheter shaft further comprises an inner polytetrafluoroethylene tubular member disposed within the polymer blend shaft (col.11, l.19-31 as the base tube or col.12, l.24-33 as the low friction layer). Regarding claims 3, 9, and 15, the catheter shaft further comprises a braided metallic support member disposed between the inner polytetrafluoroethylene tubular member and the polymer blend shaft (col.11, l.57 - col.12, l.11). Regarding claims 5-6

and 17-18, the catheter shaft further comprises a distal tip coupled to the distal portion of the catheter shaft made completely from the less rigid material (col.3, l.19-22). Regarding claim 7, the claim includes the limitations of claim 1, which is discussed above in addition to providing claimed ranges for the flexural modulus of the individual sections of the catheter shaft. The polymer blend forming the catheter shaft in which the more rigid material forming the majority of the proximal portion has a flexural modulus between 8,000 and 25,000 kg/cm^2, which overlaps the claimed range of 210 to 380ksi for the proximal portion, and the less rigid material forming the majority of the distal portion has a flexural modulus between 100 and 4000 kg/cm^2, which overlaps the claimed range of less than 30ksi (col.9, l.44-57). The intermediate portion obviously has a flexural modulus that falls within the claimed range of 30 to 90ksi, because the intermediate portion contains a substantial amount of both of the materials and therefore, would have a flexural modulus intermediate of the flexural modulus for the proximal and distal portions. Regarding claim 12, the claim is a generalized recitation of claim 3 already taught above. Regarding claim 14 and 21, the inner layer comprises polyethylene (col.11, l.19-31 as the base tube or col.12, l.24-33 as the low friction layer). Regarding claim 16,

the support member includes a coil (col.12, l.4-6). Regarding claim 19, Itou et al teach that the catheter shaft taught is used in the manufacture of a balloon catheter (col.23, l.21-32) having the limitations of claim 2 shown above, and would necessarily have a balloon coupled to the distal portion of the outer tubular member in order to be considered a balloon catheter. Regarding claim 22, the inner tubular member defines a guidewire lumen extending therethrough (col.12, l.41-47). Regarding claim 23, the balloon catheter obviously contains an inflation lumen between the inner tubular member and outer tubular member because the catheter is a balloon catheter and balloon catheters require an inflation lumen.

Itou et al fail to explicitly teach that polyoxymethylene is chosen as the more rigid material and that the polyether polyester is chosen as the less rigid material. However, Utsumi et al teach that in the art of forming catheters having a varying rigidity longitudinally throughout the catheter, polyester elastomer such as polyether polyester taught by Itou et al is commonly used as a the flexible material, and polyoxymethylene taught by Itou et al is commonly used as a rigid material. One of ordinary skill in the art would have recognized that Itou et al teach that polyoxymethylene and polyether polyester are materials that are used in the formation

of the polymer blend layer of the catheter of Itou et al and that polyoxymethylene is a known torque transmitting material for formation of rigidity varying catheters and that polyether polyester is a known flexible material for formation of rigidity varying catheters, as taught by Utsumi et al.

Therefore, it would have been obvious to select polyoxymethylene as the more rigid material of Itou et al and polyether polyester as the less rigid material of Itou et al, since polyoxymethylene is known in the art as a commonly used rigid material for this particular purpose and polyether polyester is known in the art as a commonly used flexible material for this particular purpose, as taught by Utsumi et al, and it would be obvious to select materials form the group taught in Itou et al to produce the catheter shaft of Itou et al.

Regarding claims 4 and 10, Itou et al teach that the proximal portion, intermediate portion, and distal portion define a total shaft length and that the lengths of the individual regions depend on the shape, kind, etc., of the catheter, and are not particularly limited (col.26, l.10-12). Itou et al goes on to teach the lengths of the regions with regard to one particular type of catheter, in which the proximal portion (formed of regions 22 and 23 combined) is 580 to 1150

mm, the intermediate portion (region 24) is 20 to 80mm, and the distal portion (region 25) is 5 to 20mm (col.26, l.12-20). Note the region 26 is the distal tip. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to select the lengths of the individual portions within the claimed ranges, since the lengths would be determined based on the size, kind, type, etc., of the catheter and based on the fact that the cited example teaches length ranges that overlap with the claimed ranges.

ANSWERS TO APPLICANT'S ARGUMENTS

7. Applicant's arguments regarding the 35 U.S.C. 103 rejections of claims 1-10 and 12-25 over Itou in view of Utsumi have been fully considered but they are not persuasive.

In response to Applicant's argument that Itou fails to teach the claimed ranges of about 91% to about 95% polyoxymethylene and about 5% to about 9% polyether polyester in the proximal portion of the catheter shaft. By claiming about 91% to about 95% the range includes values slightly less than 91% and slightly greater than 95%. Since about is not specifically defined in the specification, one of ordinary skill in the art would expect that about would be defined based on what values would round up to 91% and down to 95%. Therefore,

the claimed range is determined to define at least 90.5% to 95.49%. Applicant has admitted in the remarks that Itou teaches a ratio of 1:0.1, which is a value of 90.9% and 9.1%. In the same manner the claimed about 5% to about 9% is determined to define at least 4.5% to 9.49%. Thus, the ratio taught by Itou of 1:0.1 teaches values that fall within the claimed ranges.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher P. Bruenjes whose telephone number is 571-272-1489. The examiner can normally be reached on Monday thru Friday from 8:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher P Bruenjes
Examiner
Art Unit 1772

CPB CPB
July 29, 2006

JENNIFER C. MCNEIL
SUPERVISORY PATENT EXAMINER
7/30/06